UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	Docket No. 9297
Upsher-Smith Laboratories, Inc. a corporation,	)	
and	)	
American Home Products Corporation, a corporation.	)	

AMERICAN HOME PRODUCTS CORPORATION'S MOTION TO COMPEL COMPLAINT COUNSEL TO CONFINE THEIR THEORIES TO THE ALLEGATIONS IN THE COMPLAINT

Complaint counsel have taken the extraordinary step of sending an unsolicited letter to counsel for respondent American Home Products Corporation (AHP) to "clear up some apparent confusion regarding the allegations in the Commission's complaint as they relate to ESI [a unit of AHP] and the competitive harm caused by the Schering-ESI agreement." (Exhibit 1) Complaint counsel's letter purports to provide a "summary of a theory of harm, which reflects – but also expands on – the allegations in the complaint."

Rule 3.15 and the Commission's precedents prohibit complaint counsel from pursuing a theory that is not pled in the complaint. The Commission's precedents also make clear that the type of change complaint counsel is propounding is the very type of alteration in a complaint's underlying theory that only the Commission can authorize. Because the Commission has not approved the unpled theory that complaint counsel now advance, and because AHP does not in any way consent to complaint counsel's

inappropriate attempt to amend the Commission's complaint, this Court should order complaint counsel to confine their theories in this case to those that are pled in the Commission's complaint.

THE RELEVANT FACTS

As the Court is aware, the complaint alleges that AHP and Schering-Plough Corporation (Schering) entered into an agreement in 1998 to settle a patent infringement litigation, pursuant to which Schering abandoned its efforts to keep AHP and its unit ESI off the market until late in 2006, and ESI took a license that would permit it to market is allegedly infringing generic version of Schering's K-Dur 20, but only as of January 1, 2004. The complaint alleges that the parties reached an agreement "in principle" in January 1998 and a "final" agreement in June 1998.

The complaint charges against AHP only a limited theory of anticompetitive effects: that the settlement agreement delayed AHP from entering the market from March 2002 until January 1, 2004. The complaint's allegations confirm that, even in the absence of the settlement agreement with Schering, AHP could not have begun marketing its generic product before March 2002. The Commission's complaint alleges that:

> At all times relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked. Pursuant to the Hatch-Waxman Act, Upsher-Smith was eligible for the right to a 180-day Exclusivity Period for the sale of a generic version of K-Dur 20. As a result, no company could obtain final FDA approval of an ANDA to market or sell a generic version of K-Dur 20 until 180-days after Upsher-Smith first sold its product, or until Upsher-Smith's exclusivity right is relinquished, forfeited or otherwise expired. (¶ 29)
>
> Because Upsher-Smith is eligible for the 180-day Exclusivity Period, no other generic manufacturer can

> obtain a final FDA approval to market a generic version of K-Dur 20 until after the Exclusivity Period has expired, whether or not the other manufacturer has a product that infringes the Schering patent. (¶ 42)
>
> Under the Hatch-Waxman Act, the FDA is not permitted to grant final approval to a generic version of K-Dur 20, other than Upsher-Smith's Klor Con M20, until the 180-day Exclusivity Period has run. (¶ 50)
>
> ESI . . . is not eligible for final [FDA] approval until Upsher-Smith's 180-day Exclusivity Period expires. (¶ 60)
>
> Upsher-Smith's agreement with Schering not to compete with a generic version of K-Dur 20 until September 2001 has the effect of delaying entry into the relevant market by any other potential generic competitor. . . . [T]he challenged agreement delays the start of Upsher-Smith's 180-day Exclusivity Period until September 2001 and, as a result, the entry of competition from other generic manufacturers until March 2002. (¶ 66)

Thus, the Commission brought this case against AHP on the specifically-pled theory that "at all times relevant," AHP "was blocked" from obtaining FDA approval to introduce its generic drug until "Upsher-Smith's exclusivity right . . . expired" in "March 2002." Counsel for AHP pointed out during the scheduling conference on May 1 that this was the theory pled in the Complaint: "[F]rom the Commission's own complaint, Your Honor, ESI, whether or not it had settled with Schering ... could not enter because of the operation of Hatch-Waxman, until March 2002."[1]

Complaint counsel's May 30 letter astonishingly asserts that this statement "is inconsistent with the complaint's theory of competitive harm resulting from the Schering-ESI agreement, and is fundamentally at odds with the state of law at the time this

[1] May 30, 2001 Letter from Complaint Counsel to Counsel For AHP, Ex. 1 at 1, quoting statement of counsel for AHP at May 1, 2001 scheduling conference.

agreement was reached." (Ex. 1 at 1.) Complaint counsel have advised counsel for AHP – but not the Court or the Commission – that they intend to proceed on a different theory.

Specifically, complaint counsel indicate in their letter that they intend to proceed in this case on the theory that during "the critical 7 months," ESI was a "potential competitive threat[]" to Schering because "Upsher's eligibility for [the Hatch-Waxman 180-day exclusivity period] was in a state of legal flux and uncertainty."[2] Their letter provides as follows:

---

[2] Complaint counsel rely on the district court's opinion in *Granutec, Inc. v. Shalala*, No. 5:97-CV-485-BO (E.D.N.C., July 3, 1997) for the proposition that during "the critical 7 months" "there was a possibility that Upsher-Smith would not become entitled to the exclusivity right until after it successfully defended its patent litigation with Schering." Ex.1, at 2. The district court in *Granutec* did not include any analysis explaining why it applied the successful defense theory, nor did it discuss why it was departing from the well-reasoned holdings in the two district court opinions that had both addressed, and struck down, the successful defense theory. *See Mova Pharmaceutical Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. Jan. 23, 1997); *Inwood Laboratories, Inc. v. Young*, 723 F. Supp. 1523 (D.D.C. 1989), vacated as moot, 43 F.3d 712 (D.C. Cir. 1989). Perhaps more importantly, the *Granutec* district court's opinion was stayed by the Fourth Circuit Court of Appeals within six days of the date of its issuance, a signal that foreshadowed the Fourth Circuit's ultimate reversal of that opinion and validation of the district court's decision in *Mova*. *See Granutec, Inc. v. Shalala*, Nos. 97-1873, 97-1874 (4th Cir. July 9, 1997) (order staying the district court's injunction pending appeal) (attached as Exhibit 2). The issuance of the stay order undermines complaint counsel's assertion that the district court's opinion in *Granutec* created a "state of legal flux and uncertainty."

The *Granutec* stay order was granted six months before the tentative settlement between ESI and Schering in January 1998 and approximately one year before the final and binding settlement between ESI and Schering in June 1998. By June 1998, the *Mova* district court opinion had been affirmed by the DC Circuit, and the Fourth Circuit had reversed the short-lived district court opinion in *Granutec*, on which complaint counsel erect their new unpled theory. *See Mova*, 955 F. Supp. at 128; *Inwood*, 723 F. Supp. at 1523. Moreover, complaint counsel's assertion that the district court's opinion in *Granutec* created a "state of legal flux and uncertainty" regarding the viability of the successful defense theory during "the critical 7 months" is belied by the fact that, at that very time, Upsher could have gone into federal court in Washington, D.C. and restrained AHP from marketing its product. That is exactly what Andrx did, obtaining a March 30, 1998, ruling that kept a second ANDA filer from marketing its product *See Andrx Pharm., Inc., v. Friedman*, No. 98-0099 (D.D.C filed Mar. 30, 1998) (attached as Exhibit 3). In granting a TRO, the court, relying in part on the district court's opinions in *Inwood* and *Mova,* and rejecting the district court's opinion in *Granutec*, rejected the second filer's argument that the first filer was not entitled to Hatch-Waxman exclusivity because – as with Upsher-Smith here – it had settled, and not successfully defended, the patent infringement suit filed by the patent holder. *Id.* at 4-5. In doing so, the Court noted that the Hatch-Waxman legislation was "clear" and did not require a successful defense as a trigger to exclusivity. *Id.* at 4. In short, the FDA's successful defense theory was dead and buried before the time of the binding settlement agreement between Schering and ESI. In these circumstances, it is not surprising that that the Commission did not find a "reason to believe" the new theory that complaint counsel now seeks to add.

> [Based on your statements at the prehearing conference,] [y]ou seem to take the position (incorrectly) that the complaint does not allege ESI to be a potential competitor to Schering until March 2002, because the complaint correctly recognizes that Upsher-Smith is currently entitled to the Hatch-Waxman Exclusivity Period.
>
> ...
>
> Given this apparent misunderstanding, and to eliminate any conceivable future confusion, we have decided to provide you with the following summary of a theory of harm, which reflects–but also expands on–the allegations on the complaint.
>
> Under current law, Upsher-Smith – as the first generic applicant – is entitled to ... a 180-day Exclusivity Period for generic K-Dur 20. This means that no other manufacturer of generic K-Dur 20 may obtain FDA approval to market its product until Upsher-Smith's 180-day Exclusivity Period has expired. However, during the critical seven months between the Schering/Upsher-Smith and Schering/ESI agreements, Upsher's eligibility for this right was in a state of legal flux and uncertainty.... This legal and regulatory uncertainty in 1997 and early 1998 concerning Upsher's right to 180-day exclusivity under the Hatch-Waxman Act meant that both Upsher and ESI were potential competitive threats at the time of their respective agreements with Schering. ... Therefore, under the FDA regulation in place in January 1998 when Schering and ESI reached a settlement in principle, ESI was a threat to enter before Upsher – and before March 2002 – if the courts upheld the FDA's successful defense regulations and ESI could receive final FDA approval.

Ex. 1 at 1-2.

As best we can parse the foregoing, it appears that complaint counsel are not satisfied with the Commission's allegations and are stretching to articulate a different theory than the one alleged in the complaint. They do not go so far as to assert that AHP could actually have entered the market with its generic version of K-Dur at any time before March 2002. Such a claim would no doubt be specious, in light of the state of the

law both at the time the settlement between AHP and Schering was consummated and today. See supra n. 2. Such a claim would also be a direct repudiation of the Commission's complaint. Instead, complaint counsel apparently are attempting to assert either an additional or different theory of "harm" than the theory alleged in the complaint. The critical difference between this new theory and the theory advanced in the complaint is that complaint counsel now apparently claim that "harm" arose because in January 1998 AHP was a "threat to enter" prior to March of 2002, while the complaint explicitly recognizes that "at all times relevant herein," AHP has been and is blocked from entering before March 2002. If in fact complaint counsel mean to assert that competitive "harm" arose because AHP was erroneously perceived as a "threat to enter" before March 2002, then this is an entirely new theory of harm, and one that the Commission did not choose to include in its complaint.[3]

Complaint counsel have no authority to try a case the Commission has not pled. Only the Commission itself is authorized to make the "reason to believe" findings underlying its complaint. If complaint counsel seek to proceed on a theory other than the one set forth in the complaint, a disingenuous letter to counsel purportedly seeking to dispel "confusion" is not the appropriate course of action. Only a motion to amend the complaint directed to the Commission itself will do.

[3] It may well be that the Commission chose not to include this theory in its complaint because the theory on its face is untenable. If AHP was precluded from lawfully entering the market until a certain point in time,

Footnote continued on next page

ARGUMENT

I. ONLY THE COMMISSION CAN APPROVE A CHANGE IN THE COMPLAINT'S UNDERLYING THEORY

The Commission consistently has affirmed the principle that only it has the power to approve a change in a complaint's underlying theory against a respondent. In the leading case of *In re Standard Camera Corp.*, 63 F.T.C. 1238 (1963), the Commission noted that "where the effect of the amendment is an alteration of the underlying theory behind the complaint, ... the hearing examiner is without power to authorize it." *Id.* (*citing Food Fair Stores, Inc., 53 F.T.C. 1274 (1957)* and other cases). It further noted that the "amendment altered the underlying theory behind the complaint, and thus necessitated different determinations with respect to the belief that a violation of law had occurred and with respect to the nature and degree of the public interest involved. Decisions on factors such as these are reserved for the Commission." (*citations omitted).*[4]

Similarly, the Commission has stated that "[w]here a proposed amendment alters the 'underlying theory' of the original complaint, however, the Commission must make the determination whether to amend the complaint because only the Commission is authorized to determine whether there is reason to believe that the law has been violated and whether a proceeding on those amended charges would be in the public interest." *In*

Footnote continued from previous page

as the Commission's complaint recognizes, then the assertion that someone may have incorrectly perceived that AHP could enter before that time does not provide a foundation for proving "harm."

[4] The Commission's principles are embodied in Rule 3.15, which provides that "a Motion for Amendment of a complaint or notice may be allowed by the Administrative Law Judge only if the amendment is reasonably within the scope of the original complaint or Notice. Motions for other amendments of complaints or notices shall be certified to the Commission." Rule 3.15(a)(1).

re Champion Home Builders Co., 99 F.T.C. 397 (1982). Allowing for amendments that alter the underlying theory of the Commission's complaint, without certifying such amendments to the Commission for its approval, would "undermine the Commission's control over its prosecutorial discretion." *See In re Beatrice Foods Co.*, 101 F.T.C. 733 (1983).

While complaint counsel have not formally moved to amend the complaint, their stated intent to pursue a theory that is not pled in the complaint requires them to do so. *See In re Beatrice Foods Co.* ("when complaint counsel advised the ALJ and respondents' counsel at the very first prehearing conference, that it intended to prove a violation based on the unpled theory of the loss of potential as well as actual competition, the obligation arose under Rule 3.15(a)(1) to file a Motion for Amendment of the complaint which should have been certified by the ALJ to the Commission.") (emphasis added). If complaint counsel were to move to amend the complaint to pursue this new theory, Rule 3.15 would require this Court to certify any such motion to the Commission. *See* Rule 3.15; *see also, In re Beatrice Foods Co.*; *In re Champion Home Builders Co., In re Standard Camera Corp.*

II. COMPLAINT COUNSEL'S LETTER ALTERS THE "UNDERLYING THEORY" OF THE COMPLAINT

The Commission's precedents also establish that complaint counsel's letter reflects not just an "expansion" or paraphrasing of the complaint's allegations; it reflects a fundamental change in the complaint's underlying theory.

For instance, in *Standard Camera*, the Commission reversed an initial decision and held that a change in one word in one allegation in the complaint resulted in an unauthorized change in the underlying theory of the complaint. *See In re Standard*

Camera Corp. The Commission's complaint charged that respondent had violated Section 5(a)(1) of the FTC Act by failing to adequately mark foreign cameras to show that they were of foreign origin. In paragraph Nine, the complaint alleged that the failure to adequately mark the cameras caused the public to believe that the cameras were of "domestic" origin. At the prehearing conference, complaint counsel moved to substitute the word "other" for the word "domestic" in paragraph Nine. The amendment was allowed, and the hearing examiner ultimately found that respondent violated Section 5 because the inadequate markings caused the public to mistakenly believe that the cameras "were of other origin, presumably West German origin." *Id.* In setting aside the initial decision, the Commission reasoned that the examiner was not authorized to allow the amendment because it altered the underlying theory behind the complaint, i.e, that the inadequate markings caused the consuming public to believe that the foreign cameras were of domestic origin. *Id.*

Similarly, in *Beatrice Foods*, the Commission held that complaint counsel's intention to pursue an unpled potential competition theory, in addition to the complaint's actual competition theory, was an unauthorized attempt to alter the complaint's theory. *See In re Beatrice Foods.* In doing so, the Commission noted that there was a "very close question" as to whether a potential competition theory was within the scope of the complaint's allegations because the Commission's own precedent confirmed that there was "no clear line between actual and potential competition theories." *Id.* That notwithstanding, the Commission ultimately found that the line between the two theories "had become sufficiently distinct and well-established that a complaint pleading one theory, unless amended in accordance with Commission Rule 3.15(a)(1), would not

ordinarily allow proof primarily relevant only to the other." *Id.* The Commission further held that because the potential competition theory was not pled in the complaint, it would be "inappropriate" for the administrative law judge to consider evidence under that theory. *Id.* ("we hold that no potential competition theory of liability was pled in the complaint and that it is therefore in appropriate to consider evidence under this theory.")

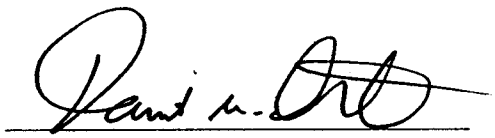
Like the new theories advanced by complaint counsel in *Standard Camera* and *Beatrice Foods*, the new theory being advanced here by complaint counsel was not pled by the Commission's in its complaint. More specifically, Paragraph 29 of the complaint, among others, provides that AHP was blocked – by operation of Upsher-Smith's Hatch-Waxman exclusivity period – from entering the market prior to March 2002, and that this was true "at all relevant times." The complaint's theory of competitive harm thus is that AHP's entry was delayed from March 2002 until January 2004. Complaint counsel now apparently contend that "harm" arose because in January 1998, AHP was a "threat to enter" before March 2002. Consistent with the holdings in *Standard Camera* and *Beatrice Foods*, this change does not merely clarify the allegations of the complaint or add examples of practices already challenged in the complaint. Instead, there can be no question that this new theory advanced by complaint counsel alters the underlying theory in the Commission's complaint.

CONCLUSION

Applying the principles set forth above, there can be no question that complaint counsel now is attempting to pursue a theory against AHP that the Commission did not plead in the complaint. Complaint counsel is not authorized to vary the allegations of the complaint where doing so alters the underlying theory of the complaint. Accordingly,

AHP respectfully requests that this Court grant AHP's Motion. AHP also respectfully requests that this Court order complaint counsel to refrain from pursuing a theory of competitive harm whereby any competitive harm results from the Schering-Plough/AHP settlement agreement before March 2002 and further prohibit them from introducing evidence for the purpose of attempting to show competitive harm from that agreement before March 2002. A proposed Order granting the requested relief is attached.

Respectfully submitted,



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(202) 942-5999 (Fax)
Counsel for American Home Products Corporation

Dated: June 15, 2001

CERTIFICATE OF SERVICE

I, David M. Orta, hereby certify that on June 15, 2001, I caused a true and correct copy of *American Home Products Corporation's Motion To Compel Complaint Counsel To Confine Their Theories To The Allegations In The Complaint* to be served upon the following persons by hand delivery or Federal Express:

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Office of the Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Richard A. Feinstein
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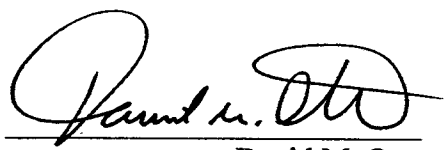

David M. Orta
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FACSIMILE TRANSMISSION SHEET

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
Bureau of Competition
Health Care Division
601 Pennsylvania Avenue, NW, S-3115
Washington, DC 20580

FROM: Brad Albert *Phone: (202) 326-3670* *Fax: (202) 326-3384*	*TO: Michael N. Sohn* *Cathy Hoffman* *Arnold & Porter* *202-942-5999* *Laura Shores* *Howry & Simon* *202-383-6610* *Christoper Curran* *White & Case LLP* *202-639-9355*
SUBJECT: Schering-Plough, Upsher-Smith, ESI Lederle, Dkt No. 9297	
COMMENTS:	

Number of pages sent (including cover sheet) 4 *Date: May 30, 2001*

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

May 30, 2001

Via first class mail and facsimile

Michael N. Sohn, Esq.
Arnold & Porter
555 Twelfth Street, N.W.
Washington, D.C. 20004

Re: Schering-Plough Corp., Upsher-Smith Laboratories, ESI Lederle, Inc., Dkt. No. 9297

Dear Mr. Sohn:

Before we move forward with discovery in this matter, we felt it important to clear up some apparent confusion regarding the allegations in the Commission's complaint as they relate to ESI and the competitive harm caused by the Schering-ESI agreement. You seem to take the position (incorrectly) that the complaint does not allege ESI to be a potential competitor to Schering until March 2002, because the complaint correctly recognizes that Upsher-Smith is currently entitled to the Hatch-Waxman exclusivity period. Specifically, you stated at the prehearing conference on May 1, 2001:

> [F]rom the Commission's own complaint, Your Honor, ESI, whether or not it had settled with Schering. . . could not enter because of the operation of Hatch-Waxman, until March 2002.

This statement, however, is inconsistent with the complaint's theory of competitive harm resulting from the Schering-ESI agreement, and is fundamentally at odds with the state of law at the time this agreement was reached. Given this apparent misunderstanding, and to eliminate any conceivable future confusion, we have decided to provide you with the following summary of a theory of harm, which reflects – but also expands on – the allegations in the complaint.[1]

Under current law, Upsher – as the first generic applicant – is entitled to what is commonly referred to as a 180-day exclusivity period for generic K-Dur 20. This means that no other manufacturer of generic K-Dur 20 may obtain FDA approval to market its product until Upsher's

[1] Of course, nothing in this letter is intended to limit complaint counsel's ability to put forth any other theory of harm consistent with the allegations in the complaint.

180-day exclusivity period has expired. However, during the critical 7 months between the Schering/Upsher-Smith and Schering/ESI agreements, Upsher's eligibility for this right was in a state of legal flux and uncertainty.

- Under FDA's regulations existing in 1997, the first ANDA applicant submitting a paragraph IV certification (Upsher-Smith) had to successfully defend a patent infringement suit before it was eligible for the 180-day exclusivity right.

- This "successful defense" requirement, however, was under attack and had been challenged in the courts. In January 1997, a federal district court rejected the FDA's "successful defense" regulation, holding that the 180-day exclusivity period should be granted to the first ANDA applicant regardless of whether the applicant had successfully defended its patent infringement suit. *Mova Pharmaceuticals Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997).

- In June 1997, Schering entered into its agreement with Upsher-Smith.

- Shortly thereafter, however, in July 1997, another federal district court upheld the FDA's successful defense regulation. *Granutec, Inc. v. Shalala*, No. 5:97-CV-485-BO (E.D.N.C. July 3, 1997).

- Schering then entered into an agreement in principle with ESI in January 1998 and dismissed its patent infringement litigation.

This legal and regulatory uncertainty in 1997 and early 1998 concerning Upsher's right to 180-day exclusivity under the Hatch-Waxman Act meant that both Upsher and ESI were potential competitive threats at the time of their respective agreements with Schering. Specifically, because of FDA's existing "successful defense" regulation, there was a possibility that Upsher would not become entitled to the exclusivity right until after it successfully defended its patent litigation with Schering. Therefore, under the FDA regulation in place in January 1998 when Schering and ESI reached a settlement in principle, ESI was a threat to enter before Upsher – and before March 2002 – if the courts upheld the FDA's "successful defense" regulations and ESI could receive final FDA approval. ESI's potential entry was a tangible threat that Schering successfully prevented.

We expect that the above explanation will clarify any confusion you had about how, according to the complaint, the Schering-ESI agreement delayed ESI's entry of a competitive generic K-Dur product. If you have any questions, please feel free to contact me.

Sincerely,

Karen Bokat

Karen Bokat
Complaint Counsel

cc: Cathy Hoffman
Christopher Curran
Laura Shores

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

Filed: July 9, 1997

No. 97-1873

GRANUTEC, INCORPORATED,

Plaintiff-Appellee,

versus

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES; MICHAEL FRIEDMAN, M.D.; FOOD & DRUG ADMINISTRATION,

Defendants,

and

GENPHARM, INCORPORATED,

Intervenor - Appellant.

No. 97-1874

GRANUTEC, INCORPORATED,

Plaintiff - Appellee,

versus

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES; MICHAEL FRIEDMAN, M.D.; FOOD & DRUG ADMINISTRATION,

Defendants - Appellees

and

GENEVA PHARMACEUTICALS, INCORPORATED,

Intervenor - Appellant.

O R D E R

We have before us the motions of Genpharm, Inc. and Geneva Pharmaceuticals, Inc. for stays pending appeal of the order of the district court filed July 3, 1997.

The order of the district court appealed from required the FDA to approve Granutec's Abbreviated New Drug Application for access to the market to sell a generic version or versions of Zantac. The stay sought for would deprive Granutec of this access during the pendency of this appeal. While Genpharm and Geneva are not agreed as to which one of them should have exclusive access to the market for a 180-day period, they are agreed in their position that Granutec should be deprived of its access to the market under the said Abbreviated New Drug Application approved by the district court.

We are of opinion that the stay of the said order of the district court should issue and that Genpharm and Geneva should enter into a sufficient supersedeas bond to make Granutec whole from any losses occasioned by delay should the order of the district court appealed from be affirmed.

It is accordingly ADJUDGED and ORDERED as follows:

1. The order of the district court appealed from, entered July 3, 1997, shall be, and it hereby is, stayed during the pendency of this appeal or until the further order of this court.

2. The condition of the bond is such that Genentech will be made whole from any losses it may suffer occasioned by delay should the order of the district court appealed from be affirmed.

3. The face amount of the bond will be $10 million, and the bond will be secured by corporate surety, to be approved by the clerk of the district court. If the amount of said bond be either too great or too small, the parties may apply to this court for a modification of this order.

4. The motions to expedite the appeal are granted, and the clerk will arrange an appropriate briefing schedule so that the case will be argued during the term of this court commencing September 29, 1997.

5. The motion of Genpharm to keep its disclosure statement under seal is denied.

With the concurrences of Judge Russell and Judge Phillips.

/s/ H. E. Widener, Jr.

For the Court

Exhibit 3

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ANDRX PHARMACEUTICALS, INC.,

Plaintiff,

v. Civil Action No. 98-0099 (JGP)

MICHAEL A. FRIEDMAN,
LEAD DEPUTY COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

MEMORANDUM

This matter is before the Court on plaintiff Andrx Pharmaceuticals' Motion for a Temporary Restraining Order. Plaintiff seeks an order directing the U.S. Food and Drug Administration ("FDA") to withdraw its approval of the Abbreviated New Drug Application ("ANDA") sponsored by Mylan Pharmaceuticals that it granted on March 18, 1998, and to prohibit any marketing by Mylan of its generic formulation of Dilacor XR® until April 8, 1998. The Court heard oral argument on the motion on March 26, 1998. The same day, the Court entered a temporary restraining order pending the Court's consideration of this motion and to permit Mylan Pharmaceuticals to file papers with Court.

In determining whether to grant emergency injunctive relief, the Court considers (1) the movant's likelihood of succeed on the merits, (2) whether the movant will suffer irreparable injury without such relief, (3) whether the nonmoving party or parties will suffer substantial harm, and (4) where the public interest lies. See Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841 (D.C. Cir. 1977).

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This case raises issues regarding statutory provisions enacted in 1984 to promote the public interest in the availability of generic drugs. Specifically at issue is whether Andrx is entitled to enjoy a 180-day period of market exclusivity for its generic version of a drug, or whether FDA properly permitted another company, Mylan Pharmaceuticals, to market its generic version of the same drug prior to the running of 180 days.

In late 1995, Andrx Pharmaceuticals ("Andrx") submitted an ANDA to FDA seeking to market its generic formulation of the cardiac drug Dilacor XR® ("Dilacor"), which is patented by Jagotec AG. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Andrx certified that Jagotec AG's patent is either invalid or would not be infringed by the manufacture, use, or sale of Andrx's generic version. According to the statutory scheme, Andrx notified Jagotec (and Dilacor's manufacturer) of its ANDA filing, and was subsequently sued for patent infringement. The patent infringement suit stayed FDA's consideration and approval of Andrx's ANDA. See 21 U.S.C. § 355(j)(4)(B)(iii). On January 10, 1997, the parties settled the patent infringement case, and on October 10, 1997, FDA approved Andrx's ANDA.

During this time, Mylan Pharmaceuticals ("Mylan") also submitted an ANDA seeking to market its own generic version of Dilacor. On March 18, 1998, the FDA approved Mylan's ANDA. Andrx maintains that FDA violated 21 U.S.C. § 355(j)(4)(B)(iv)[1] by approving Mylan's ANDA. That provision reads as follows:

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not

[1] The Court notes that the statute has recently been amended, so that the section referred to herein as 355(j)(4)(B) now appears at 355(j)(5)(B).

earlier than one hundred and eighty days after —
(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

Andrx argues that this provision prohibits FDA from approving Mylan's ANDA within 180 days of either (1) Andrx's initial marketing of its generic drug, or (2) a court decision holding the Dilacor patent invalid or not infringed. As there has been no court order holding the Dilacor patent invalid or not infringed, Andrx maintains that FDA cannot approve Mylan's ANDA until 180 days from when Andrx began marketing its generic version of Dilacor, or April 8, 1998.

FDA responds that it approved Mylan's ANDA pursuant to a regulation issued by FDA to implement the statutory provisions at issue. The specific regulation at issues is 21 C.F.R. § 314.107(c)(1), which conditions the 180-day period of exclusivity on the requirement that " the applicant submitting the first application has successfully defended against a suit for patent infringement . . . ." Thus, under FDA's regulation, in order to receive the 180-day period of exclusivity, an ANDA applicant must (1) be the first to file a paragraph IV certification, (2) be sued, and (3) successfully defend the patent infringement suit. Pursuant to this regulation, Andrx is not entitled to the 180-day period of exclusivity, and thus the approval of Mylan's ANDA was permissible, because Andrx has not "successfully defended" a patent infringement suit. Rather, Andrx settled the patent infringement suit and that settlement did not include a finding that the patent was invalid or not infringed.[2]

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[2] FDA states that a settlement of a patent suit may qualify as a "successful defense" when entry of the final judgment includes a finding that the patent is invalid or not infringed. Government Opposition at 7 n.3.

FDA maintains that the statute is ambiguous and that its interpretation is due deference because it is reasonable and consistent with the purposes of the statute. FDA argues that "the statute does not specifically address whether the exclusivity period prohibits FDA's approval of other paragraph IV ANDA applicants if the first filer is sued for patent infringement and loses, settles, or if it is not sued at all," and that "[t]hus, FDA was required to fill the gap . . . ." The Court does not agree.

The statute provides two alternative triggering dates for the running of the 180-day period: (1) the initial marketing of the prior ANDA applicant's generic drug, or (2) a court finding that the patent is not valid or not infringed. The latter alternative clearly requires the filing of a patent suit against the initial generic manufacturer.[3] The former does not. FDA's argument that the statue does not speak to whether the 180 days should run if the first ANDA applicant is never sued, is sued and settles, or is sued and loses, is not persuasive. The statue is clear, in those circumstances, the 180-day period begins to run from the initial marketing of the drug. There is simply no requirement in the statute that the first ANDA applicant must be sued. Because the statute is clear, there is no need to defer to FDA's regulatory interpretation under Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43, 104 S. Ct. 2778, 2781-82 (1984) (requiring deference to an agency interpretation if Congress has not "directly spoken to the precise question at issue" and if the agency interpretation is reasonable).

Two other judges of this Court have held against FDA on this precise issue, holding that the statute is not ambiguous. In Mova Pharmaceutical Corp. v. Shalala, 955 F. Supp. 128

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[3] In fact, by its terms the second alternative requires a suit for patent infringement pursuant to section 355(j)(4)(B)(iii).

(D.D.C. Jan. 23, 1997), appeal pend'g, Nos. 97-5082, 97-5111, Judge Robertson, discussing the provision at issue here, held that Chevron deference was not required because "the statute is neither 'silent [n]or ambiguous.'" Id. at 130 (alteration in original). The court further held that "[t]he language of the statute may be complex, and even cumbersome, but it is plain and unambiguous. It does not include a 'successful defense' requirement, and indeed it does not even require the institution of patent litigation." Id.; see also Inwood Laboratories, Inc. v. Young, 723 F. Supp. 1523, 1526 (D.D.C. 1989) ("Section 355(j)(4)(B)(iv) explicitly provides that a primary generic manufacturer may qualify for the 180 day exclusivity in one of two ways--by compliance with subpart I or by compliance with subpart II. . . . The two alternatives are clear, and they establish a complete and workable statutory scheme. . . . There is no ambiguity in the provisions of subpart I that requires the Court or permits the FDA to read into it a requirement of a lawsuit which is simply not there."), vacated as moot, 43 F.3d 712 (D.C. Cir. 1989).

The parties have provided the Court with an order entered by the District Court for the Eastern District of North Carolina which purportedly holds contrary to the courts in this district. See Granutec, Inc. v. Shalala, No. 97-cv- 485, (Order dated July 3, 1997). The court in that case determined that pursuant to its regulation, FDA was required to approve an ANDA to a second applicant because the first applicant had not "successfully defended" a patent suit. Id. at 3. In Granutec, however, the court did not address the conflict between the statute and the regulation.

It is apparent to the Court that both FDA and the intervenor seem concerned not so much about ambiguity as about what it considers unfavorable results of applying the clear statutory language. These potential scenarios do trouble the Court. However the Court also notes that perverse results could obtain from permitting FDA to follow its regulation. For example, the

circumstances presented to the court in Mova were that the first ANDA applicant was tied up in patent litigation and had never gone to market, thus had had no benefit of the 180-day period of exclusivity, at the time FDA approved the second ANDA. This too is a result seemingly inconsistent with a statutory provision intended to reward the first ANDA applicant for risks associated with being the first generic drug to seek FDA approval. Other, similarly troublesome, situations may also result. See Inwood, 723 F. Supp. at 1526-27 (discussing possible outcomes of applying FDA regulation).[4]

In light of these facts, the Court finds that Andrx has demonstrated a strong likelihood of success on the merits.

The Court further finds that Andrx would be harmed by not receiving the full benefit of the 180-day period of market exclusivity to which it is entitled. Although the period of time at issue is rather short, all parties agree that the industry in which Andrx competes is exceedingly competitive and that each day on the market is worth a large amount of money. Moreover, what is at issue is not simply money, but market share. The Court further notes that where, as here, the likelihood of success on the merits is strong, a lesser showing of irreparable injury is required to obtain relief. See, e.g., Mova, 955 F. Supp. at 131 (citing Cuomo v. United States Nuclear Regulatory Comm'n, 772 F.2d 972, 974 (D.C. Cir. 1985) (per curiam)).

The intervenor vigorously argues that it will be substantially harmed by the entry of an

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[4] In Inwood, the court noted, for instance, that "[u]nder the FDA's interpretation, if the patent holder chooses to sue only the second, the third, or the fifth applicant, the rather bizarre result will be that no one is entitled to exclusivity." 723 F. Supp. at 1526. The court further noted that "[b]y subjecting the exclusivity entitlement to the caprices of the patent holder, the FDA's interpretation would seem to affect adversely the incentives that Congress sought to create in providing for 180 days of exclusivity for the manufacturers of generic drugs." Id. at 1527.

order prohibiting them from marketing their product until April 8, 1998. Specifically, Mylan argues that it stands to lose $1.6 million and will suffer harm to its reputation because it will have to renege on promises to ship orders "immediately". Mylan's Opposition at 10-11. However, because the Court has found that it is likely that Mylan's ANDA should not have been granted until April 8, the "harm" to which Mylan refers amounts primarily to losing what it should never have had — the opportunity to market and sell its product from March 18 to April 8. Although there may be other harm to Mylan--such as delayed shipment of orders already placed--the Court finds that the balance of the factors weigh in favor of granting a temporary restraining order.

Finally, the Court finds that the public interest in the faithful application of the statute outweighs the public interest in making Mylan's generic drug available nine days earlier.

For the foregoing reasons, the Court will enter an appropriate order directing Mylan to cease the marketing, sale, and distribution of its generic version of Dilacor until April 8, 1998. Although Andrx requested an order directing the FDA to withdraw its approval of Mylan's ANDA, the Court finds that such an order could compound the harm to Mylan by calling into question the action already taken by Mylan in reliance on FDA's action. Thus, and since Mylan is now a party to this action, the Court will address its order directly to Mylan.

The Court will also order that Andrx post a bond in the amount of $500,000.

Date: MAR 30 1998
5:30 p.m.

JOHN GARRETT PENN
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FILED

MAR 30 1998

NANCY MAYER-WHITTINGTON, CLERK
U.S. DISTRICT COURT

ANDRX PHARMACEUTICALS, INC.,

Plaintiff,

v. Civil Action No. 98-0099 (JGP)

MICHAEL A. FRIEDMAN,
LEAD DEPUTY COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

ORDER

This matter is before the Court on plaintiff Andrx Pharmaceuticals' **Motion for a Temporary Restraining Order**. For the reasons set forth in the accompanying memorandum, it is hereby

ORDERED that plaintiff's **Motion for a Temporary Restraining Order** is granted, and it is further

ORDERED that Intervenor Mylan Pharmaceuticals cease the marketing, sale, and distribution of its generic version of Dilacor XR® until April 8, 1998, and it is further

ORDERED that Andrx Pharmaceuticals must post a bond in the amount of $500,000.

Date: MAR 30 1998
5:30 p.m.

JOHN GARRETT PENN
United States District Judge

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